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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/522,215 | 04/07/2005 | Elias Castanas | P/567-129 | 1523 |

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| EXAMINER | |
|---|---|
| LUKTON, DAVID | |
| **ART UNIT** | **PAPER NUMBER** |
| 1654 | |

DATE MAILED: 12/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/522,215 | CASTANAS, ELIAS | |
| | Examiner | Art Unit | |
| | David Lukton | 1654 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *02 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-27* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The following abbreviations are used hereinbelow:

**S/MP conjugate**: a conjugate comprising a steroid and a mammalian protein

**CAD**: a "cytoskeleton acting drug"

**AAA**: an antiandrogen or an antiestrogen or an antiprogestin, or all three of the foregoing

. . . .

Restriction to one of the following inventions is required under 35 U.S.C. §121:

1 ) Claims 1-4, 11, 12, 26, drawn to a method of preparing a pharmaceutical composition, wherein the composition comprises an S/MP conjugate, but does not contain a CAD or an AAA.

2 ) Claims 5-6, drawn to drawn to a method of preparing a pharmaceutical composition, wherein the composition comprises a combination of an S/MP conjugate and a CAD, but an AAA is not present.

3 ) Claims 7-10, drawn to drawn to a method of preparing a pharmaceutical composition, wherein the composition comprises a combination of an S/MP conjugate and a AAA, but a CAD is not present.

4 ) Claims 13-17, 27, drawn to a composition which comprises a combination of an S/MP conjugate and a CAD, but an AAA is not present.

5 ) Claim 18, drawn to a composition comprising a ternary mixture of an S/MP conjugate, a CAD and an AAA.

6 ) Claims 19-21, drawn to a method of treating a cancer or hematological malignancy.

7 ) Claims 22-23, drawn to a method of detecting the presence of a solid cancer or a hematological disorder.

8 ) Claims 24-25, drawn to a kit comprising an S/MP conjugate and either of the following: (a) a CAD or (b) an AAA.

The claimed inventions are distinct.

Groups 3 and 2 are related as combination/subcombination; groups 2 and 1 are also related as combination/subcombination. The S/MP conjugate can be used by itself, or with the CAD or with the AAA. However, in the event that Group 1 is elected, and claims therein found allowable, it is likely the case that Group 2 and 3 claims would be rejoined (with those found allowable), if those non-elected claims required all of the limitations of the allowed claims, and required also the presence of a CAD or an AAA.

Inventions 4 and 6 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). However, in the event that group 4 is elected, and claims therein found allowable, claims drawn to a method of using the allowed compositions will be rejoined for further examination.

Applicant is advised that for the response to this requirement to be complete, an election of the invention to be examined must be indicated, even if the requirement is traversed (37 C.F.R. 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must

be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

. . . .

In addition to the foregoing, applicants are required under 35 U.S.C. §121 to elect disclosed species (as follows) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

In the event that Group 1 is chosen for initial examination, election of a specific composition is required, with all constituent compounds accounted for. The structure of the conjugate should be provided, or else sufficient textual description that the structure can be determined. Note that claim 1 mandates the presence of at least two compounds, since it is drawn to a method of making a composition. Accordingly, all constituent compounds should be accounted for.

. . . .

In the event that Group 2 is chosen for initial examination, election of a specific composition is required, with all constituents accounted for, including the S/MP conjugate and the CAD.

. . . .

In the event that Group 3 is chosen for initial examination, election of a specific and fully defined composition (that is the product of the claimed "use" ) is required.

. . . .

In the event that Group 4 is chosen for initial examination, election of a specific composition is required, with all constituents accounted for, including the S/MP conjugate and the CAD.

. . . .

In the event that Group 5 is chosen for initial examination, election of the following is required:

a ) one of the following: (i) the AAA consists of all three of the following: an antiandrogen, an antiestrogen, and an antiprogestin, or (ii) the AAA consists of just one of the following: an antiandrogen, an antiestrogen, and an antiprogestin;

b ) a fully defined composition

. . . .

In the event that Group 6 is chosen for initial examination, election of the following is required:

a ) a specific composition in which all constituents are accounted for, including the S/MP conjugate and the CAD;

b ) a specific cancer (e.g., prostate adenocarcinoma) or "hematological condition" that is to be treated;

. . . .

In the event that Group 7 is chosen for initial examination, election of the following is required:

a ) a specific conjugate;

b ) a specific tissue that constitutes the specimen;

c ) a specific disease (i.e., cancer or hematological condition) with which the subject is afflicted.

. . . .

In the event that Group 8 is chosen for initial examination, election of a specific kit is required, with all constituents of the kit accounted for.

. . . .

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a generic claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are witten in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentable distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. ∋103 of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed

product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

✦

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached at (571)272-0974. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

DAVID LUKTON
PATENT EXAMINER
GROUP 1800